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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/744,328	01/23/2001	Satoshi Sasaki	Q62621	4446

7590 02/25/2004

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EXAMINER	
KAM, CHIH MIN	
ART UNIT	**PAPER NUMBER**
1653	

DATE MAILED: 02/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No.	Applicant(s)	
	09/744,328	SASAKI ET AL.	
	Examiner	**Art Unit**	
	Chih-Min Kam	1653	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 04 February 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☐ The period for reply expires _____months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked.· Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1.☒ A Notice of Appeal was filed on *2/4/04*. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2.☒ The proposed amendment(s) will not be entered because:

(a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);

(b) ☐ they raise the issue of new matter (see Note below);

(c) ☒ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

(d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: *See Continuation Sheet*.

3.☒ Applicant's reply has overcome the following rejection(s): See Continuation Sheet.

4.☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5.☒ The a)☐ affidavit, b)☐ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *See Continuation Sheet*.

6.☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7.☒ For purposes of Appeal, the proposed amendment(s) a)☒ will not be entered or b)☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____.

Claim(s) objected to: _____.

Claim(s) rejected: *1,3,6,11,12,25,30 and 35*.

Claim(s) withdrawn from consideration: *5,7-10,17,19-22,29 and 31-34*.

8.☐ The drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9.☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.

10.☒ Other: *attached form 1449*

Christopher S. F. Low

CHRISTOPHER S. F. LOW
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Continuation of 2. NOTE: The amendment to the claims does not resolve the current issues under 35 USC 112, first paragraph. It also raise new issues regarding the method for preventive treatment of glomerular nephritis, diabetic nephropathy or tissue fibrosis, which require further consideration. In the amendment of February 4, 2004, claims 6, 11, 12, 25 and 30 have been amended, claims 3 and 35 have been cancelled, and a new claim 37 has been added. Applicants' response has been fully considered, however, claims 1, 6,11,12, 25, 30 and 37 are rejected under 35 USC 112, first paragraph.

If applicants' amendment were entered, it would have the following response:

1. Claims 1, 6,11,12, 25, 30 and 37 are rejected under 35 USC 112, first paragraph, because the specification, while being enabling for a pharmaceutical composition comprising an identified compound such as LNFP-I that inhibits the biological activity of galectin-3, which promotes the production of extracellular matrix from an extracellular matrix-producing cell; or a method for inhibiting the overproduction and accumulation of extracellular matrix, comprising administering an identified compound that inhibits the binding of galectin-3 to the extracelluler matrix in the extracelluler matrix-producing cells, does not reasonably provide enablement for a pharmaceutical composition having inhibitory effect on glomerular nephritis, diabetic nephropathy or tissue fibrosis comprising a compound that inhibits the biological activity of galectin-3; or a method for therapeutic or preventive (not even occur at the first time) treatment of glomerular nephritis, diabetic nephropathy or tissue fibrosis caused by the overproduction and accumulation of extracellular matrix, comprising administering a compound having an inhibitory effect on the biological activity of galectin-3 to a subject, wherein the compound is not defined because the specification only indicates certain galectin-3 binding inhibitors such as fetuin glycoprotein and LNFP-1 inhibit galectin-3 binding and the promotion of collagen type IV production in rat mesangium cells (see Examples 5 and 6), it does not show the in vivo treating conditions such as the amount of the compound administered, nor demonstrates the effects of a specific galectin-3 inhibitor in the treatment of the cited diseases in vivo, especially in the preventive treatment of diseases, e.g., if the disease does not occur, how to monitor the effect of the administered compound. Moreover, there are no teachings on how to extrapolate the in vitro data to in vivo treatment, and no working examples for in vivo treatment. Since the specification does not provide sufficient teachings on the treating conditions such as the dose,the time, thus, it is necessary to carry out further experimentation to assess the effect of the the compound that inhibits the biological activity of galectin-3 for in vivo treatment of the cited diseases. In response, applicants indicate substances that inhibit galectin-3 repress the promotion by galectin-3 of the production and accumulation of the type IV collagen in the type IV collagen-producing cells, and a method for testing inhibitory activity of galectin-3 are described in Examples 5 and 6 of the specification; the specification (pages 6-8) also identify 6 types of compounds as inhibitors of galectin-3; it is known in the art that an accumulation of extracellular matrix (ECM) causes the diseases recited in the claim, the present invention is based on the discovery that galectin-3 promotes the accumulation of extracellular matrix, thus, it is reasonable to expect that a substance that inhibits the activity of galectin-3 would be suitable to treat the cited diseases; and two more references submitted demonstrate a correlation between the accumulation of ECM and diseases, and the ability to alleviate symptoms of diseases by inhibiting accumulation of collagen (pages 8-11 of the response). The response has been fully considered, however, the argument is found persuasive because the in vitro data in the specification only indicates two specific galectin-3 binding inhibitors repress the production and accumulation of the type IV collagen in the type IV collagen-producing cells, it does not provide sufficient teachings on the in vivo effect of various compounds in treating or preventing the cited diseases. The submitted references indicate a compound such as a mutant PAI-1 inhibits accumulation of collagen and alleviates the symptoms of glomerular nephritis in an animal model, but the compound is not a galectin-3 inhibitor. As indicated in the previous Office Action, the specification has not demonstrated how to apply the in vitro data to in vivo effect, thus without further experimentation it is not known whether various compounds with diverse structures that inhibit galectin-3 biologival activity via different mechanism would be effective in treating or preventing the cited diseases in vivo. Therefore, it is necessary to have further experimentation to assess the effects of various compounds that inhibit galectin-3 biological activity in treating the cited diseases.

Continuation of 3. Applicant's reply has overcome the following rejection(s): If entered, the rejection of claims 25, 30 and 37 under 35 USC 112, second paragraph.

Continuation of 5. does NOT place the application in condition for allowance because: The amendment to the claims does not resolve current issue under 35 USC 112, first paragraph for claims 1, 6,11,12, 25, 30 and 37 .

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571) 272-0951. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 308-4227 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Chih-Min Kam, Ph. D. CMK
Patent Examiner

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February 20, 2004